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Applicant's election without traverse of group I, claims 1-13 and 15-21, in Paper No. 13 is acknowledged.

The specification incorrectly states that the instant application is a continuation of 08/063,095, rather than a continuation-in-part. The specification should either be amended to indicate that the application is a continuation-in-part or to delete all new matter not found in the parent application.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 15-21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 5,523,226. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods recite essentially the same process steps. The only difference is that the instant claims omit the step of passaging the cells through a SCID mouse to check for pluripotency. Also the species "swine" of the patented claims anticipates the genus "ungulate" of the pending claims.

Claims 1-13 and 15-21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14-16 and 48-50 of copending Application No. 08/473,030. Although the conflicting claims are not identical, they are not patentably distinct from each other because the process steps are essentially the same in the two applications, and the species "swine" of 08/473,030 anticipates the genus "ungulate" of the pending claims.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-6, 9-13 and 15-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for swine, does not reasonably provide enablement for all ungulates. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The specification does not provide any working examples or specific guidance regarding production of embryonic stem (ES) cells of species other than swine. The parent application disclosed methods limited to production of swine ES cells. In the instant application, the specification has been amended to allege that the methods which were shown to be effective for swine are also effective for other ungulate species. There is reason to doubt this assertion, given the unpredictable nature of the art. Mammalian species differ in their embryonic development. Differences among species are acknowledged by Applicant (specification, p. 5). Cruz et al. (A20) list some of the differences in early embryonic development among swine, oxen, horses, goats and sheep (e.g. Table 1). Bazer et al. (A11) also provide an overview of differences among ungulate species (entire document). Piedrahita et al. (A52) observed that porcine and ovine embryos responded differently to the same treatments. Conditions which allowed production of porcine ES-like cell lines did not allow development of ovine ES-like cell lines (e.g. Table 1). Piedrahita et al. state, "Ovine intact embryos and isolated ICM behaved differently than porcine embryos" (p. 888). Furthermore, those skilled in the art recognize that not all "ES-like" cells are "true" ES cells, i.e. totipotent cells capable of contributing to the germ line of chimeric animals. The specification acknowledges the need to "validate" ES cells (p. 10). In conclusion, it would require undue experimentation for one skilled in the art to extend the disclosed methods to species other than swine. This is particularly true given the nature of the invention, the state of the prior art, the breadth of the claims, the amount of experimentation necessary, the scarcity of specific guidance and lack of working examples in the specification, and the unpredictable nature of the art.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Kashiwazaki et al. This rejection could be overcome by amending the claims to recite a "cultured" ES cell.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kashiwazaki et al. Kashiwazaki et al. disclose a method for producing chimeric pigs (entire document). Kashiwazaki et al. do not disclose a method in which one of the parental breeds is Meishan, nor do they disclose methods in which the ES cell has an exogenous DNA sequence integrated into its genome.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods of Kashiwazaki et al. by using a Meishan pig or a transgenic pig as the source of stem cells to be transplanted into the recipient blastocyst. The skilled artisan would have been motivated to do so in order to produce an improved breed. There would have been a reasonable expectation of success, since there was no reason to believe that Meishan or transgenic pig ES cells would behave differently from the breed used by Kashiwazaki et al. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. This rejection could be overcome by amending the claims to recite "cultured" ES cells.

Claim 3 is deemed free of the prior art.

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce Campell, whose telephone number is 703-308-4205. The examiner can normally be reached on Monday-Thursday from 8:30 to 5:00 (Eastern time). The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jasmine Chambers, can be reached on 703-308-2035. The FAX phone number for art unit 1819 is 703-308-0294.

An inquiry of a general nature or relating to the status of the application should be directed to the group receptionist whose telephone number is 703-308-0196.

Bruce Campell
March 13, 1997

BRUCE R. CAMPPELL
PRIMARY EXAMINER
GROUP 1800